REMARKS/ARGUMENTS

Status of the Application

In the Office Action, claims 31-34 and 47-48 were rejected. No amendments were made to the claims in the present response. Claims 49-51 were added (see page 24, lines 1-9, for support). Thus, claims 31-34 and 47-51 are pending. No new matter was added.

Rejections Under 35 U.S.C. § 101

Claims 31-34 and 47-48 were rejected under 35 U.S.C. § 101 as not being supported by either a specific and substantial asserted utility or a well-established utility. Applicant respectfully traverses these rejections.

Submitted herewith is a declaration under 37 C.F.R. § 1.132 signed by the Applicant, Liat Mintz, Ph.D., which establishes a specific and substantial utility for the claimed inventions. Dr. Mintz describes a series of experiments, also attached hereto, which demonstrate that administration of acylated ghrelin variant 2 (SEQ ID NO:32) to mice produces the same growth and food consumption response as the wild type acylated protein. Further, unlike wild type des-acyl ghrelin, des-acyl ghrelin variant 2 apparently reduces growth and the food consumption response in mice.

Dr. Mintz stated that she utilized an experimental procedure known in the literature for analyzing growth and food consumption. Indeed, the only difference between Dr. Mintz's procedure and that used in Tschöp *et al.* was Dr. Mintz' use of a lower dosage amount of test compounds, a change based on later experiments by other research groups. Route of administration, frequency of administration, and duration of administration were all performed as described in Tschöp *et al.*

The results of Dr. Mintz's experiments are as follows. The cumulative body weight gain of the SEQ ID NO:32-treated and the wild type ghrelin-treated 129Sv mice was significantly higher than the vehicle-treated controls. The cumulative body weight gain of the des-acyl SEQ ID NO:32-treated 129Sv mice was significantly lower than the vehicle-treated controls. In contrast, no significant differences were observed in the cumulative body weight gain between wild type des-acyl ghrelin-treated and vehicle-treated 129Sv mice. Further, the

cumulative food consumption of the SEQ ID NO:32-treated and the wild type ghrelin-treated 129Sv mice was significantly higher than the vehicle-treated controls. The cumulative food consumption of the des-acyl SEQ ID NO:32-treated 129Sv mice was significantly lower than the vehicle-treated controls. In contrast, no significant differences were observed in the cumulative food consumption between wild type des-acyl ghrelin-treated and vehicle-treated 129Sv mice.

Dr. Mintz concluded that "acylated SEQ ID NO:32, like wild type ghrelin, significantly promotes body weight gain and food consumption. Des-acyl SEQ ID NO:32 significantly promotes weight loss and decreased food consumption, unlike wild type des-acyl ghrelin which has no significant influence on body weight and food consumption."

Applicant thus respectfully submits that a specific and substantial utility has been established for the claimed inventions. "A claimed invention must have a specific and substantial utility. This requirement excludes 'throw-away,' 'insubstantial,' or 'nonspecific' utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101." MPEP § 2107(II)(B)(1)(i). The asserted utility here is specific because the experiments tested the growth and food consumption response of ghrelin variant 2. The asserted utility is substantial because increasing or decreasing the growth and/or food consumption of mice is a "real world" utility. *See Id.* § 2107.01(I)(B) ("A 'substantial utility' defines a 'real world' use"). Applicant further notes that the specified utility in mice is sufficient under section 101 and that a showing of usefulness in humans is not required. *Id.* § 2107.01(III). ("Office personnel should not construe 35 U.S.C. 101, under the logic of 'practical' utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans.")

The asserted utility is also credible. "Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions." MPEP § 2107(II)(B)(1)(ii). Because Dr. Mintz used an established procedure in analyzing the growth and food consumption response that was

essentially the same as disclosed in the literature, one of ordinary skill in the art would consider the asserted utility to be credible.

Consequently, Applicant respectfully submits that, because a credible specific and substantial utility has been established for the claimed inventions, the utility rejection has been traversed.

Rejections Under 35 U.S.C. § 112, 1st Paragraph

Claims 31-34 and 47-48 were rejected under 35 U.S.C. § 112, 1st Paragraph, as not providing one skilled in the art with the knowledge to use the claimed inventions, because the claimed inventions allegedly were not supported by either a specific and substantial asserted utility or a well-established utility. Applicant respectfully submits that, because the utility rejection above has been traversed, these rejections under 35 U.S.C. § 112, 1st Paragraph, have also been traversed.

Claims 33 and 34 were rejected under 35 U.S.C. § 112, 1st Paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses these rejections.

Applicant respectfully submits that the interpretation of the specification is incorrect. To satisfy the written description requirement, an applicant must demonstrate to one of ordinary skill in the art that the applicant is in possession of the invention at the time the application is filed. MPEP § 2163.02. Here, the specification discloses the amino acid sequence of ghrelin variant 2 (SEQ ID NO:32) and states that "protein fragments having at least 10 contiguous amino acid residues" are within the scope of the disclosure (page 49, lines 5-6). Because the *original* disclosure covers every possible fragment of SEQ ID NO:32 having at least ten amino acids, amending the claims to cover a smaller scope logically includes the same disclosure.

To illustrate, every fragment of SEQ ID NO:32 of at least ten amino acids is disclosed by the specification. Included is the 37-117 fragment of SEQ ID NO:32 (because it has at least ten amino acids). Every fragment of the 37-117 fragment is disclosed because these fragments are necessarily disclosed within the entire sequence of SEQ ID NO:32. One of ordinary skill in the art through a

routine use of a computer program could readily list the entire set of fragments having at least ten amino acids from SEQ ID NO:32. An applicant should not have to produce such lists as the written description requirement only mandates that an applicant have possession of the invention. It is unclear here how one of ordinary skill in the art would not recognize that the Applicant possesses all fragments of SEQ ID NO:32 of at least ten amino acids.

Claims 33-34 and 47-48 were rejected under 35 U.S.C. § 112, 1st Paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses these rejections.

Applicant incorporates the arguments above in response to this rejection. As with the above arguments, the present claims provide a narrower scope as compared to the original disclosure. The original disclosure supports fragments of SEQ ID NO:32 having 90% identity thereto. All fragments within the scope of a subset of SEQ ID NO:32 logically must also be disclosed by the specification.

Summary

In view of the foregoing amendments and remarks, Applicant submits that this application is in condition for allowance. In order to expedite disposition of this case, the Examiner is invited to contact Applicant's representative at the telephone number below to resolve any remaining issues. Should there be a fee due which is not accounted for, please charge such fee to Deposit Account No. 501447 (Potter Anderson & Corroon LLP).

Respectfully Submitted,

By: _____

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